Treatment of the Medial Meniscus with the NUsurface® Meniscus Implant. A Prospective, Multi-Center, Open Label, Non-randomized Study of the NUsurface® Meniscus Implant

Published: 03-07-2013
Last updated: 24-04-2024

To evaluate the safety, device-related complications, and performance of the NUsurface® meniscus implant as a device for the treatment of patients with degenerative and/or tears of the medial meniscus. .

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON41631

Source
ToetsingOnline

Brief title
NUsurface Meniscus Implant

Condition

- Joint disorders

Synonym
medial meniscus deficiency, medial meniscus torn

Research involving
Human

Sponsors and support

Primary sponsor: Active Implants Corporation
Source(s) of monetary or material Support: Active Implants Corporation

Intervention

Keyword: Medial Meniscus, Meniscally deficient Knee, NUsurface Meniscus Implant

Outcome measures

Primary outcome

Safety

1.Incidence (including severity) of operative and immediate post-operative

device-related complications through 30 days post intervention.

2.Incidence of all adverse events through the 6, 12, and 24 months

post-operative period.

3.Incidence of secondary surgical intervention through the 6, 12, and 24 month

post-operative period.

Device-related complications

Device-related complication is defined as a complication found to be caused by

the device and device malfunctions (including severity), as assessed at each

post-op period. Device malfunctions include expulsion and device fracture.

Records of secondary surgical intervention will be maintained.

Performance

To assess the performance of the NUsurface® Meniscus Implant through the 12 and

24 months post-operative periods using the KOOS Pain Sub-scale and the overall

KOOS scale relative to baseline.

Secondary outcome

Not applicable

Study description

Background summary

Tears of the meniscus are a common source of knee pain. Clinical assessment of meniscus tears includes non-operative and operative treatment options. Non-operative treatment includes physical therapy, bracing, rest, activity modification, analgesics, and inflammatory reduction measures such as icing, non-steroidal anti-inflammatory medications and occasionally corticosteroid injections. Non-operative treatment is usually instituted and followed for approximately six weeks, and patients typically return to full activities after three months. If the patient does not improve, then surgery must be considered

Operative treatment includes *menisci tears repairs` to relief pain through tear resection or repair while preserving as much of the meniscus as possible. Allograft implantation*` with primary indication for the surgery being A sympyomatic patient having undergone a previous meniscectomy with persistent pain in the involved compartment and who has failed non-operative treatment.
Other operative treatment are
Meniscal scaffolds and Interpositional devices.
Each of the above treatment options has limitations.

The majority of the aforementioned treatment options are designed primarily to treat younger patients, most often suffering from traumatic tears rather than degenerative tears that are most common in people 35 years old and above. Because of poor regenerative capabilities usually found in these patients, surgeons are unlikely to choose any of these treatment options. On the other hand, more aggressive procedures like Unicompartmental Knee Arthroplasty or Total Knee Arthroplasty may fit in a more severe condition of the cartilage, e.g., grade 4 OB and relate to older patients (60+), that in many cases, have three-compartmental disease. Thus, a *treatment gap* can be defined between the two approaches . Active Implants strongly believes that the NUsurface® Meniscus Implant can be the preferred treatment that will meet the significant demand

from this patient population in the *treatment gap.*

Study objective

To evaluate the safety, device-related complications, and performance of the NUsurface® meniscus implant
as a device for the treatment of patients with degenerative and/or tears of the medial meniscus. .

Study design

This study is a prospective, multi-center, open label, non-randomized study.

Intervention

All patients fulfilling the criteria for participation in the trial will be implanted with the NUsurface Meniscus Implant, which received CE Mark approval in March 2008
The NUsurface devices are available in numerous sizes and are available for left and right medial meniscus.

The procedure is performed a under anesthesia. The meniscus implant is inserted during an arthroscopy through a small knee incision (4- 6cm).
The size of the NUsurface implant will be determined based on pre-operatively X-rays scans trial implants during the intervention.

Study burden and risks

The burden for the patients is that they have to undergo a more extensive post operative follow up and rehabilitation progam compared to standard patients outside this study.

The possible risks of this study are risks associated in general in surgeries, risks specific for orthopaedic knee implants and add.
The Risks associated with NUsurface®:
The expected life of meniscal implant is difficult to estimate. These components are made of foreign materials which are placed within the body to help with the potential restoration of mobility and/or the reduction of pain. However, because of the many biological, mechanical and physicochemical factors which affect these devices, the components cannot be expected to withstand the loads of normal healthy meniscus indefinitely.

The meniscus implant surgery can reduce or eliminate knee pain and improve mobility of the patient. It could be that the need for more complex procedure

such as a unicompartmental or total knee prosthesis is postponed.

Contacts

Public
Active Implants Corporation

5865 Ridgeway Center Parkway Suite 218
Memphis TN 38120
US
Scientific
Active Implants Corporation

5865 Ridgeway Center Parkway Suite 218
Memphis TN 38120
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

To be included in the NUsurface study the patient must have medial compartment knee pain and ALL of the following conditions:
1.Have a degenerative and/or torn meniscus and/or previous meniscectomy as confirmed by diagnostic MRI.
2.Have a pain score of 75 or less on the KOOS pain scale, with 100 being normal.
3.Be in neutral alignment +/- 5 degrees of the mechanical axis.
4.Be between age 35 and 75 at the time of the planned surgery.
5.Be able to be fitted anatomically with a size 30 to 90 NUsurface® device.
6.Have a normal mental status.

7.Be willing and able to attend all follow up visits, complete all study questionnaires, and undergo required X-ray and MRI schedule.
8.Be able and willing to understand and sign the informed consent form.

Exclusion criteria

The patient is excluded from the study if ANY of the following conditions are met for the involved knee:
1.Have evidence of a Grade IV articular cartilage loss on the medial tibial plateau or femoral condyle that could contact the NUsurface implant
2.Have lateral compartment pain with lateral articular cartilage damage greater than Grade II (OB), and/or a lateral meniscus tear(s)
3.Have a varus or valgus knee deformity > 5 degrees.
4.Have a laxity level of more than II (ICRS), secondary to previous injury of the anterior cruciate ligament (ACL) and/or posterior cruciate ligament (PCL) and/or lateral collateral ligament (LCL) and/or medial collateral ligament (MCL).
5.Have patella instability or non-anatomically positioned patella
6.Have patellar compartment pain and/or patellar articular cartilage damage greater than Grade II (OB).
7.Need a tibial osteotomy at the time of surgery.
8.Have an ACL reconstruction performed less than 9 months before implanting the NUsurface® device
9.Have any type of previously implanted prosthetic meniscus or ligament or knee implant made of plastic.
10.Have a knee flexion contracture > 10 degrees
11.Be unable to flex the knee to 90 degrees
12.Have a leg length discrepancy causing a noticeable limp.
13.Have had a previous major knee condyle surgery
14.Present with insufficiency fractures or avascular necrosis of the medial compartment.
15.Have an active infection or tumor.
16.Have any type of knee joint inflammatory disease including Sjogren*s syndrome.
17.Have neuropathic knee osteoarthropathy, also known as Charcot joint.
18.Have any medical condition that does not allow arthroscopy at the point of entry to the knee.
19.Be pregnant or is a female intending to become pregnant during the study period.
20.Be mentally incapacitated.
21.Be a prisoner.
22.Be a patient who has economic incentive not to improve (e.g., workman*s compensation patient)
23.Be morbidly Obese (BMI > 35).
24.Is unwilling or unable to have an X-ray, Fluro, or MRI of the affected knee

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-08-2013
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	NUsurface® meniscus implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-07-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	17-06-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01712191
CCMO	NL43323.068.13

Study results

Date completed: 02-02-2016

Actual enrolment: 3

Summary results
Trial is onging in other countries